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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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November 24, 2015

Dr. Richard Frank
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Frank:

Thank you for appearing before the Subcommittee on Health on October 8, 2015, to testify at the hearing entitled "Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 8, 2015. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Representative Joseph R. Pitts

1. Dr. Frank, a number of questions at the hearing focused on the Department's announcement related to the current DATA 2000 patient caps.

    a. Can you please explain the factors that will be considered in determining how to raise these caps while limiting the potential for diversion?

    b. How will differences in various settings at which buprenorphine can be prescribed and/or administered be considered? Are you considering expanding the type of settings at which buprenorphine can be prescribed and/or administered? If so, how?

    c. How will differences in certain types of patients or products be considered when determining whether and how to change the current limitations?

2. Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives, should CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids? How could CMS most efficiently develop and advance such quality metrics? How might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?

3. CMS is in a position to impact the prescription drug abuse crisis more significantly, using a variety of levers at its disposal. In addition to curbing the risk of abuse in Part D, CMS could also take steps to reduce the overuse of opioids by Medicare providers in the surgical setting. There is a growing number of alternatives to opioids, often referred to as multimodal analgesia, that manage pain in the acute care setting without using more addictive opioids. According to the American Society of Anesthesiologists Task Force on Acute Pain Management, there is strong support for the use of such alternatives to minimize the unnecessary use of opioids (Anesthesiology, 2012).

    a. Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives; wouldn't you agree that CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids?

    b. How could CMS most efficiently develop and advance such quality metrics?

    c. Do you agree that this is a reasonable goal and if so, how might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?

4. Should patients addicted to opioids receive treatment based on their individual clinical needs? How does HHS intent to incorporate this principal into its recently proposed rule?

5. Dr. Frank, should patients be able to choose from among all FDA-approved medications for opioid use disorder in any given treatment setting? Is that currently possible – why or why not?

6. How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?

7. IOM recommended creation of a national strategy to transform how pain is assessed, understood and treated. Dr. Frank, has HHS made any progress on this front?

8. Improving professional education about opioid prescribing and appropriate pain management is critical. What is the government doing to improve provider education across the spectrum of disciplines and throughout the continuum of undergraduate, graduate and continuing health profession training?

The Honorable Representative Tim Murphy

1. On September 17, Secretary Burwell announced that HHS would be revising the regulations related to buprenorphine dispensing in the physician office setting to "safely and effectively increase access."

    a. What is the timeframe you anticipate for this action and how, if at all, are you engaging with stakeholders to inform this process?

    b. Throughout this process, what attention is being given to the threat of drug diversion associated with the higher levels of supply envisioned?

    c. How can an effective drug diversion control plan assist in reducing the incidence of diversion? What are its limitations?

    d. How does the Secretary's initiative account for extended engagement and monitoring of patents by medical and addiction professionals?

9. How do federal privacy rules surrounding the sharing of patient alcohol and substance abuse data – such as 42 CFR Part 2 – frequently obstruct communication between healthcare providers or even among state agencies? What, if anything, can be done about this?

10. How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?

The Honorable Representative Gus Bilirakis

1. Dr. Frank, how will HHS ensure that patients receive comprehensive, effective treatment if the patient caps are raised without requiring physicians at DATA 2000 clinics to have the capacity to provide other services, such as counseling and patient monitoring?

2. Are there regulations in place to ensure that buprenorphine provided at these clinics is not diverted?

3. Patients suffering from opioid addiction not only need treatment using prescription drugs, but also need comprehensive support services like counseling and patient monitoring. It is my understanding that under the DATA 2000 law, clinics are not required to offer any of these services. Since you spoke of the importance of medication-assisted treatment, which includes other therapy services, why shouldn't DATA 2000 clinics be required to adopt these patient-centered practices if they wish to raise patient caps?